USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Voluntary Report - Public distribution

Date: 8/31/2007

GAIN Report Number: JA7053

Japan

Agricultural Situation

MRL Changes to Toltrazuril, Flunixin, Marbofloxacin, and Meloxicam

2007

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Report Highlights:
On August 10, MHWL announced proposed standards for veterinary drugs, Toltrazuril, Flunixin, Marbofloxacin, and Meloxicam. MHLW will notify these changes to the WTO SPS Committee.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Tokyo [JA1]
[JA]

The Japanese Ministry of Health Labour and Welfare (MHLW) announced in early-August proposed to set up new standards for four animal drugs. Three chemicals (Toltrazuril, Marbofloxacin, and Meloxicam) are currently not permitted to use in food animals in Japan. One, Flunixin, was reassessed on the basis of regal requirement. The period for comments directly to MHLW closed at August 17, 2007, however MHLW will notify these proposed changes to the WTO/SPS committee, which would be the last chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a report to the Minister of Health, Labour, and Welfare will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

If you need to contact FAS Tokyo, please send an inquiry to the Agriculture Section of the U.S. Embassy in Tokyo, at agtokyo@usda.gov.

Summary

Establishment of Standards for the Veterinary Drugs (Toltrazuril, Flunixin, Marbofloxacin, Meloxicam) in Food

Purpose

This activity is to develop specifications and standards for foods. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare may establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as “agricultural chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed unless such food complies with the established standards. On May 29, 2006 the Ministry of Health, Labour and Welfare introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system. Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese market place if it contains agricultural chemicals at amounts exceeding certain levels specified under the Law.

Outline of the activity

Toltrazuril (Anticoccidial drug): The chemical is not permitted for use in food animals in Japan. In response to an application made by a foreign business for the establishment of standards, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on February 5, 2004, the MHLW has newly established some MRLs. Also, the MHLW has reviewed the existing MRLs for the substance.

Flunixin (Non-steroidal anti-inflammatory drug): The chemical is permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries (MAFF) has reassessed a drug product whose effective ingredient is Flunixin. This is on the basis of the legal requirement stating that veterinary drugs, once approved, must be reassessed every six years. In addition, MAFF has decided to expand the scope of target animals for which the use of the chemical is permitted. In response to MAFF’s action, the MHLW has reviewed the existing MRLs for the substance.

Marbofloxacin (synthetic antibacterial drug): The chemical is not permitted for use in food animals in Japan. MAFF has decided to approve drug products whose effective ingredient is Marbofloxacin. In response to MAFF’s action, the MHLW has reviewed the existing MRLs for the substance.

Meloxicam (Non-steroidal anti-inflammatory drug): The chemical is not permitted for use in food animals in Japan. MAFF has decided to approve a drug product whose effective ingredient is Meloxicam. In response to MAFF's action, the MHLW has reviewed the existing MRLs for the substance.

The MRLs for these chemicals, which currently appear in the Provisional MRLs List (Item 7, Section A "General Compositional Standard for Food," Part 1 "Food" in the Specifications and Standards for Food, Food Additives, Etc), have been modified as necessary. The finalized MRLs will be placed on the MRLs List (Item 6, Section A), and the MRLs placed in Item 7 will be deleted. For draft MRLs, see Attachment 2-1 for Toltrazuril, Attachment 2-2 for Flunixin, Attachment 2-3 for Marbofloxacin, and Attachment 2-4 for Meloxicam.

Attachment 2-1

Toltrazuril (Anticoccidial drug)

Commodity	Draft MRL[1] (ppm)	Current MRL (ppm)
Cattle, muscle	0.1	
Pig, muscle	0.5	0.3
Terrestrial mammals other than above, muscle	0.1	
Cattle, fat	0.3	
Pig, fat	0.5	0.6
Terrestrial mammals other than above, fat	0.2	
Cattle, liver	1	
Pig, liver	2	2
Terrestrial mammals other than above, liver	0.5	
Cattle, kidney	0.5	
Pig, kidney	1	1
Terrestrial mammals other than above, kidney	0.5	
Cattle, edible offal[2]	0.5	
Pig, edible offal	0.5	2
Terrestrial mammals other than above, edible offal	1	
Chicken, muscle	1	0.9
Poultry other than above, muscle	0.5	0.3
Chicken, fat	2	0.2
Poultry other than above, fat	1	0.2
Chicken, liver	4	2
Poultry other than above, liver	2	0.8
Chicken, kidney	4	2
Poultry other than above, kidney	2	0.7
Chicken, edible offal	3	3
Poultry other than above, edible offal	2	1
Chicken, egg		0.05
Poultry other than above, egg		0.05

1. MRLs for toltrazuril are expressed as the sum of residues of three substances (toltrazuril-sulfone and toltrazuril-sulfoxide, both calculated as toltrazuril, and toltrazuril).
2. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.

Attachment 2-2

Flunixin (Non-steroidal anti-inflammatory drug)

Commodity	Draft MRL (ppm)	Current MRL (ppm)
Cattle, muscle	0.02	0.02
Pig, muscle	0.03	0.05
Terrestrial mammals other than above, muscle	0.01	0.03
Cattle, fat	0.03	0.03
Pig, fat	0.2	0.01
Terrestrial mammals other than above, fat	0.02	0.05
Cattle, liver	0.3	0.2
Pig, liver	0.2	0.2
Terrestrial mammals other than above, liver	0.1	0.05
Cattle, kidney	0.1	0.1
Pig, kidney	0.03	0.03
Terrestrial mammals other than above, kidney	0.2	0.05
Cattle, edible offal[1]	0.3	0.1
Pig, edible offal	0.2	0.03
Terrestrial mammals other than above, edible offal	0.2	0.05
Milk	0.04	0.02

1. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.

Attachment 2-8

Marbofloxacin (synthetic antibacterial drug)

Commodity	Draft MRL (ppm)[1]	Current MRL (ppm)[1]
Cattle, muscle	0.1	0.2
Pig, muscle	0.05	0.2
Cattle, fat	0.05	0.05
Pig, fat	0.05	0.05
Cattle, liver	0.1	0.2
Pig, liver	0.05	0.2
Cattle, kidney	0.15	0.2
Pig, kidney	0.1	0.2
Cattle, edible offal[1]	0.05	0.2
Pig, edible offal	0.05	0.2
Milk	0.075	0.08

1. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.

Attachment 2-4

Meloxicam (Non-steroidal anti-inflammatory drug)

Commodity	Draft MRL (ppm)[1]	Current MRL (ppm)[1]
Cattle, muscle	0.02	0.02
Pig, muscle	0.01	0.02
Terrestrial mammals other than above, muscle	0.02	0.02
Cattle, fat	0.02	0.02
Pig, fat	0.01	0.1
Terrestrial mammals other than above, fat	0.02	0.02
Cattle, liver	0.05	0.07
Pig, liver	0.01	0.06
Terrestrial mammals other than above, liver	0.02	0.07
Cattle, kidney	0.05	0.1
Pig, kidney	0.01	0.09
Terrestrial mammals other than above, kidney	0.1	0.07
Cattle, edible offal[1]	0.05	0.07
Pig, edible offal	0.01	0.06
Terrestrial mammals other than above, edible offal	0.1	0.07
Milk	0.02	0.01

1. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.